

# West Nile Virus



## Update

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# WNV Human Infection

WNV in humans	1999	2000	2001	2002	2003	2004	2005
Disease (n~20, 000)	62	21	66	4,156	9,862	2,539	3,000
Fatal cases (n=785)	7	2	9	284	264	100	119

Neuroinvasive cases (n=8,386)	59	19	64	2,942	2,866	1,142	1,294
Estimated # infections (~1,300,000)	8,850	2,850	9,600	441,300	429,900	173,000	194,100

## Transmission by Transfusion

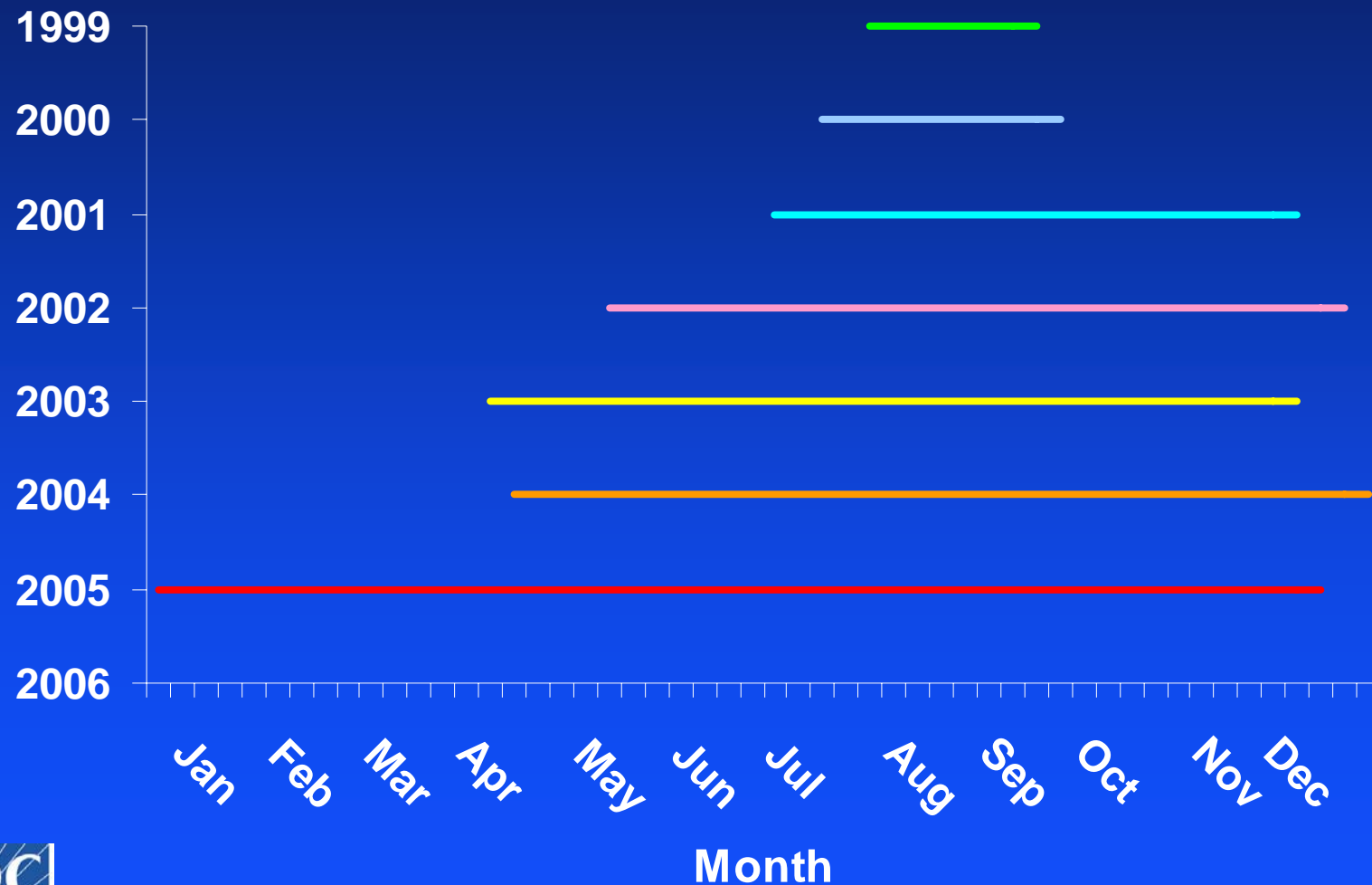
PVD (n > 1,600)				~1000	>1,000	221	399
TT confirmed* (n=30)				23	6 ‡	1 ‡	0
TT inconclusive <sup>+</sup> (n=26)				19	6	1	0

\*All seronegative for WNV; + Lack of f/up, sample, recipient loss

‡ Negative in MP-NAT and positive on ID-NAT (low viremia)



# Onset of Human WNV Disease, United States 1999-2005\*



\*Reported as of 2/14/2006



# History of WNV and Blood safety

## 2002

- Identification of risk for WNV in the blood safety
- Initiative of OBRR/CBER call for test development
- Collaboration between Government, Academia, Industry and Blood establishments

## 2003

- Development and nationwide implementation of blood screening for WNV by MP-NAT (6 or 16 donations) under FDA approved INDs
- Interdiction of WNV reactive donations made by asymptomatic donors
- Evaluation of MP-NAT sensitivity by retrospective studies

## 2004 and 2005

- ID-NAT replaced MP-NAT in specific areas of high WNV activity during limited periods of time



# Status of WNV Assays

- FDA licensed the first WNV NAT for volunteer blood donor screening (Procleix® WNV Assay on eSAS) in December 2005
- Other WNV NAT for donor screening are currently under IND

# Current Considerations: Assay Implementation

- ❁ We recognize that WNV RNA NAT for testing samples from volunteer blood donations for transfusion may involve the use of complex pooling and testing systems
- ❁ We are considering recommending the implementation of licensed NAT for WNV RNA within six months from the date of the publication of a Notice in the Federal Register announcing the availability of the final guidance

# Current Considerations: Testing

- ❖ WNV became endemic in the US with intense activity re-occurring between spring and fall
- ❖ The screening of volunteer donors of Whole Blood and blood components for transfusion for WNV RNA will improve the safety of the nation's blood supply
- ❖ WNV screening by MP-NAT should be performed year-round, with implementation of ID-NAT in specific geographical areas where WNV activity is high
- ❖ Criteria to trigger ID-NAT in a given geographical area, and to revert back to MP-NAT, should be defined and validated by the centers, based on incidence rates

# Current Considerations: Testing

- ✿ We are considering recommending confirmation of initial reactivity in the index donation by retesting that donation
  - a. using the same assay in duplicate
  - b. using alternate NAT with sensitivity comparable to that of the screening assay
- ✿ Encourage the use of antibody testing on the initial donation

# Current considerations: Donor Management

WNV is a communicable agent to the CDC

- ❁ Reasonable attempts to be made to notify deferred donors of test results
- ❁ We encourage additional testing to be performed as follows:
  - a. Alternate NAT and antibody testing in the index donation may provide information for donor counseling purposes
  - b. Follow-up testing may provide further information on the course and outcome of infection, and antibody testing may work as a confirmatory tool

# Considerations on Labeling

We are considering recommending:

- ❖ The container label and instruction circular that reflects the results of WNV NAT be consistent with the labeling for other infectious disease markers upon implementation of licensed NAT
- ❖ WNV reactive unit not be shipped or used except as provided in FDA approved programs and/or research or autologous use only and such units be labeled with appropriate warnings

# Current Considerations for:

Donor Deferral and Reentry

Unit Management

Recipient Notification

Are to remain as stated in the June 2005

Guidance: [WWW.fda.gov/cber/gdlns/wnvguid.htm](http://WWW.fda.gov/cber/gdlns/wnvguid.htm)

